Application No. Applicant(s) 10/672.144 TAMARKIN ET AL. Office Action Summary Examiner Art Unit J. E. ANGELL 1635 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 16 May 2011. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 27,28,31 and 40-42 is/are pending in the application. 4a) Of the above claim(s) _____ is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) ☐ Claim(s) 27 and 28 is/are rejected. 7) Claim(s) 31 and 40-42 is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) because to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) ☐ All b) ☐ Some * c) ☐ None of: Certified copies of the priority documents have been received. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s)

U.S. Patent and Trademark Office PTOL-326 (Rev. 08-06)

Notice of References Cited (PTO-892)

Paper No(s)/Mail Date _

Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)

Interview Summary (PTO-413)
 Paper No(s)/Mail Date.

6) Other:

5) Notice of Informal Patent Application

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DETAILED ACTION

This Action is in response to the communication filed on 5/16/2011.

Claims 27, 28, 31, 40-42 are currently pending.

Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

Claim Rejections - 35 USC § 103

- The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all
 obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fitzgerald et al.
 (Cell 1983, cited in 10/14/2010 IDS) in view of Leizer et al. (Blood 76(10), 1990; pages 1989-1996), for the reasons or record.

Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over
 Fitzgerald et al. (Cell 1983, cited in 10/14/2010 IDS) in view of Lorberboum-Galski et al.
 (PNAS 85, 1988; pages 1922-1926), for the reasons or record.

Response to Arguments

Applicant's arguments filed 5/16/2011 have been fully considered but they are not persuasive as they apply to the rejection of claims under 35 U.S.C. 103.

Applicant argues that Fitzgerald does not teach the use of a colloidal gold complex comprising a cytokine and a target molecule, or a colloidal gold complex comprising PE-EGF, referring to the Experimental Procedures section.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the rejected claim(s) only requires that one or more cytokines and a target molecule are "admixed with or bound to a colloidal metal" (emphasis added). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, it is noted that the specification of Fitzgerald specifically teaches:

Using electron microscopy, we find that adenovirus and epidermal growth factor attached to colloidal gold (EGF-Au) enter KB cells together via coated pits and receptosomes. At

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5 min, adenovirus begins to appear free in the cytosol and promotes the release of EGF-Au into the cytosol. Pseudomonas toxin (PE) also is internalized via coated pits and receptosomes. Adenovirus enhances the toxicity of PE 100-fold, and enhances a conjugate of PE and epidermal growth factor (PE-EGF), which enters cells via the EGF receptor, 10,000-fold. These results suggest that adenovirus disrupts receptosomes, enhancing delivery of material contained in them into the cytosol.

It is also noted that, as previously indicated, the specification does not particularly define the term "target molecule", but it is clear that the term encompasses molecules that bind to a receptor on the cell surface (e.g., see paragraphs [0085], [0088], etc.). Since the EGF binds to a cell surface receptor (EGFR), it would necessarily be a targeting molecule, as well as a cytokine

Therefore, the teachings of Fitzgerald are sufficient to teach the limitations of claim 27, except for the administration to a human or animal.

Therefore, Applicant's arguments are not persuasive.

Claim Objections

Claims 31, 40-42 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE

MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. E. ANGELL whose telephone number is (571)272-0756. The examiner can normally be reached on Monday-Thursday 7:00 a.m.-5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Heather Calamita can be reached on 571-272-2876. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. E. ANGELL/ Primary Examiner, Art Unit 1635